K130014

SAKAE CORPORATION
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510(k) Summary

APR 0 4 2014

1 Applicant

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2 Contact Information:

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3 Device Trade Name:

A1c GEAR System

4 Device Common Name:

Glycated hemoglobin assay and discrete photometric chemistry analyzer for clinical use

5 Manufacturer Address

SAKAE CORPORATION
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Phone: (81)-274-52-3126 Fax: (81)-274-52-4240

6 Device Classification:

SAKAE CORPORATION A1c GEAR System (new) is a Class II device and reagent, and is classified by FDA under 21 CFR 864.7470 Glycosylated hemoglobin assay and the FDA Product Code is LCP.

A1c GEAR (the instrument) is a Class I device and is classified by FDA under 21 CFR 862.2160, Discrete photometric chemistry analyzer for clinical use, and the FDA Product Code is JJE.

7 Device Description:

The A1c GEAR instrument is a fully automated desktop electric spectrophotometer that measures %HbA1c in human whole blood using a dedicated reagent (MEDIDAS HbA1c). The system illuminates a 660 nm LED (Light Emitting Diode) through the test material and quantitatively measures the percent of hemoglobin A1c in the total hemoglobin (%HbA1c) by means of light absorbance changes and a non-linear calibration curve. The system includes the Hemoglobin A1c Analyzer (A1c GEAR), thermal printer, barcode reader, power cable, and fan filter.

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MEDIDAS HbA1c is composed of a test cartridge, capillary, pipette tip and master calibration card. The cartridge is pre-filled with reagent; latex (reagent R1), antibody (reagent R2), and sample dilute solution.

8 Indications for Use

The A1c GEAR System is intended for in vitro diagnostic use only for the quantitative measurement of the percent hemoglobin A1c (%HbA1c) from finger-stick blood or venous whole blood collected in either EDTA or sodium fluoride (NaF) for clinical laboratory and point of care use. The measurement of HbA1c is recommended to monitor long-term glycemic control of persons previously diagnosed with diabetes mellitus. This test is not for screening or diagnosis of diabetes.

9 Limitations

- This test should not be used in monitoring daily glucose control.
- Should not be used to replace daily home testing of urine and blood glucose levels.
- Should not be used for analyzing samples from patients with conditions causing shortened red blood cell survival, such as hemolytic diseases, pregnancy and significant acute or chronic blood loss.

10 Expected Values and Reference (non-diabetic) Level

The American Diabetes Association (ADA) expected value range is 4.0-6.0% HbA1c for people without diabetes.

The American Diabetes Association's (ADA) most recent Clinical Practice recommendation for diabetes specified a treatment goal of less than 7% and suggests additional action when HbA1c is above 8%

HbA1c Value	**Glycemic Goal**
<8% HbA1c	Less stringent
<7% HbA1c	General (Non-Pregnant Adults)
<6.5% HbA1c	More stringent

American Diabetes Association Standards of Medical Care in Diabetes 2012, 35 (Supplement1), S11-S63

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11 Predicate Device

DCA Vantage, a test system for hemoglobin A1c by Siemens Medical Solutions Diagnostics, K071466. The predicate device has the same intended use, uses substantially the same assay methodology, and is substantially equivalent to the A1c GEAR System.

Device Comparison Chart

Manufacturer	**SAKAE CORPORATION**	**Siemens Medical Solutions Diagnostics**
Trade Name	**A1c GEAR System**	**DCA Vantage**
510(k) Number	K130014	K071466
Product Code	LCP	LCP
Regulation Number	864.7470	864.7470
Indications for use:	Quantitative measurement of percent hemoglobin A1c in human whole blood	Quantitative measurement of percent hemoglobin A1c in human whole blood
Methodology	Immuno-turbidimetric	Immuno-turbidimetric (inhibition)
Sample	Finger-stick blood or venous whole blood collected in K2 EDTA or sodium fluoride	Finger-stick blood or venous whole blood collected in EDTA, heparin, fluoride/oxalate, and citrate
Visual Display	LCD	LCD
Hemolysate preparation	Automatic	Automatic
Detection Method	Transmission	Transmission
Calibration	User; calibration card	User; calibration card
Recommended testing environment	Professional use; point of care	Professional use; point of care
Throughput	6-7 minutes per sample	6-7 minutes per sample
Analytical Range	4.3-12.5%	2.5-14.0%
Reagent Storage	2-8 degrees Celsius (36-46 degrees Fahrenheit)	2-8 degrees Celsius (36-46 degrees Fahrenheit)
Accuracy (Comparison)	Versus HPLC method Y=1.03x-0.33, R=0.99 N=158	Versus DCCT reference method (HPLC) Y=1.02x-0.00, R=0.98 N=100
NGSP Certification Status	Certified	Certified
Complies with IEC 60601-1	Yes	Yes
Complies with IEC 60601-1-2	Yes	Yes

12 Performance Data

12.1 Linearity

Linearity of the A1c GEAR System was verified with the use of two whole blood samples collected into EDTA tubes. Sample low (L: 4.0% HbA1c, result from ion-exchange HPLC) and high (H: 15.0% HbA1c, result from ion-exchange HPLC) were mixed in different proportions to obtain a series of 11 samples. All samples were measured in triplicate. Recovery rate was used as an indicator for the degree of the deviation of expected values. The linear regression analysis was performed.

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Table 1 Linearity of the A1c GEAR System. Y: observed value, X: expected value, r^2: squared coefficient of correlation, recovery (%) = observed value / expected value x 100.

Range (% HbA1c)	Regression line	r^2	Recovery (%)
4.0 - 13.1	y =0.98x + 0.19	1.00	98 - 103

12.2 Method Comparisons (venous to venous sampling, in-house)

Method comparison studies were performed with three comparison methods; two different ion-exchange HPLC methods and one point of care (POC, DCA Vantage) method were each compared to the A1c GEAR System. Venous whole blood collected into EDTA tubes were prepared from donors and analyzed.

Table 2 Linear regression analysis data of method comparison. Y: A1c GEAR, X: comparison method, N: number of samples, r^2: squared coefficient of correlation.

Comparison Method	N	HbA1c (%)	Regression Line	r^2
HPLC 1	158	4.6-10.6	y = 1.03x - 0.33	0.98
HPLC 2	40	4.2-9.8	y = 0.99x + 0.31	0.98
Another POC analyzer (DCA Vantage)	60	4.7-11.7	y = 0.95x - 0.12	0.99

12.3 Matrix Comparison

Matrix comparison studies were performed to evaluate the effect of the sample matrix. A finger-stick sample and venous whole blood samples with anticoagulants EDTA or sodium fluoride (NaF), were collected from each donor and analyzed with the A1c GEAR System.

Table 3 Linear regression analysis data of matrix comparison. N: number of samples, r^2: squared coefficient of correlation.

Matrix	N	HbA1c (%)	Regression line	r^2
finger (y) vs. EDTA-venous (x)	78	4.3-9.0	y = 0.96x + 0.15	0.99
NaF-venous (y) vs. finger (x)	46	4.8-8.8	y = 1.04x - 0.06	0.99
NaF-venous (y) vs. EDTA-venous (x)	81	5.3-10.9	y = 1.01x + 0.01	0.99

12.4 Precision

Precision studies were performed at both internal and external sites. The studies followed CLSI (Clinical and Laboratory Standards Institute) Guideline EP5-A2.

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Within-run (repeatability), between-day, and total precision were determined for two control materials (control L and H) and three EDTA whole blood samples at the internal site, and with two control materials (control L and H) and two EDTA whole blood samples at the external site. The samples were analyzed for 20 days, in duplicate, twice a day (n = 80).

Table 4 Results from the internal site. %CV: %coefficient of variation.

Sample	N=	Mean	Within-run CV (%)	Between-day CV (%)	Total CV (%)
Control L	80	5.2	1.26	0.51	1.36
Control H	80	9.0	0.85	0.26	1.06
Sample 1	80	5.5	0.73	0.80	1.12
Sample 2	80	11.1	1.11	0.70	1.37
Sample 3	80	12.1	1.14	1.01	1.52

Table 5 Results from the external site. %CV: %coefficient of variation.

Sample	N=	Mean	Within-run CV (%)	Between-day CV (%)	Total CV (%)
Control L	80	5.0	1.08	0.75	1.31
Control H	80	8.9	0.65	0.53	0.90
Sample 1	80	5.2	1.18	0.56	1.34
Sample 2	80	8.8	0.82	0.47	1.05

Table 6 Reproducibility estimated from the results of two sites. %CV: %coefficient of variation.

Sample	N	Overall mean	Between-site CV (%)	Total CV (%)
Control L	160	5.1	2.55	2.81
Control H	160	9.0	0.56	0.94

12.5 Point of Care (POC) Studies

External validation of the A1c GEAR System was performed at POC sites to evaluate precision and method comparisons.

In the precision study, three levels of controls were analyzed for 20 days and three levels of patient samples were analyzed for 10 days by POC operators.

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Table 7 Results of precision study at three external sites. %CV: %coefficient of variation.

Sample	N =	Site	Mean	Within-site CV (%)	Overall mean	Reproducibility Total CV (%)
Control 1	120	1	5.19	2.85%	5.22	2.26%
	120	2	5.21	1.92%		
	120	3	5.27	1.46%		
Control 2	120	1	7.01	2.53%	7.06	2.11%
	120	2	7.07	1.73%		
	120	3	7.10	1.73%		
Control 3	120	1	11.05	3.37%	11.04	2.55%
	120	2	11.09	2.48%		
	120	3	11.00	1.35%		
Sample Low	60	1	5.80	3.14%	5.84	3.12%
	60	2	5.83	3.28%		
	60	3	5.89	2.63%		
Sample Middle	120	1	8.01	3.31%	8.07	4.16%
	128	2	7.87	2.30%		
	120	3	8.34	2.91%		
Sample High	120	1	10.55	3.22%	10.84	5.25%
	128	2	10.59	2.46%		
	120	3	11.38	3.21%		

In the method comparison study, a finger-stick sample and a venous EDTA sample were collected from each donor. The finger-stick blood samples were analyzed with the A1c GEAR System by POC operators and the venous blood samples were analyzed with an ion-exchange HPLC (Tosoh, G8) reference method by qualified laboratory technicians at a reference laboratory.

Table 8 Linear regression analysis of method comparison study at three external sites. N: number of samples, r: coefficient of correlation.

Study site	N	Min	Max	Slope (95% confidence interval)	Intercept (95% confidence interval)	r
1	47	4.9	11.9	0.968 (0.941 to 0.994)	0.04 (-0.16 to 0.24)	0.995
2	41	5.4	10.8	0.976 (0.936 to 1.015)	0.12 (-0.15 to 0.40)	0.990
3	46	5.0	9.6	0.989 (0.952 to 1.027)	0.08 (-0.18 to 0.35)	0.990

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12.6 Interference

No significant interference was observed up to the following concentrations in both EDTA and NaF whole blood samples, or commercial controls:

▪ Free - bilirubin	37.0 mg/dl
▪ Conjugated - bilirubin	40.4 mg/dl
▪ Rheumatoid factor	550 IU/ml
▪ Chyle (mixture of lipids)	3120 FTU (Formazine Turbidity Unit)
includes:	
Triglycerides	170 mg/dl
Phospholipids	182 mg/dl
Free fatty acids	124 µEq/dl (approx. 1.24 mmol/l)
▪ Triglycerides (separate study)	2,000 mg/dl
▪ Acetaminophen	20.0 mg/dl
▪ Ibuprofen	50.0 mg/dl
▪ Glibenclamide	0.2 mg/dl
▪ Metformin	5.1 mg/dl
▪ Ascorbic acid	6.0 mg/dl

NOTE: It is possible that other substances and/or factors not listed above may interfere with the test and cause false results.

12.7 Analytical Specificity

12.7.1 Hemoglobin (Hb) Variants

A hemoglobin variant study was performed using commercial samples known to contain Hemoglobin variants C, D, E, S and F. Samples contained both low and high levels of %HbA1c at concentrations from 4.6-11.6%. These variant samples were tested in duplicate using the A1c GEAR System versus a reference method (Primus Ultra Boronate Affinity HPLC). The results indicated samples containing Hemoglobin C were elevated by 24%, samples containing Hemoglobin D were elevated by 16%, samples containing Hemoglobin E were elevated by 13% and samples containing Hemoglobin S were elevated by 14%. Samples containing >10% Hemoglobin F were decreased by 32%. All variants tested were shown to interfere with this device.

12.7.2 Modified Hemoglobin

The following modified hemoglobin was prepared by incubating with the substance in parentheses and found not to affect the A1c GEAR System for both EDTA and NaF whole blood samples:

- Carbamylated hemoglobin (sodium cyanate, 10 mg/dl)
- Acetylated hemoglobin (acetylsalicylic acid, 200 mg/dl)
- Labile hemoglobin (D-glucose, 2000 mg/dl)

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12.8 Limit of Detection

To estimate the lowest detectable value of %HbA1c for the A1c GEAR System, limit of detection (LOD) studies were performed and LOD was calculated to be 2.6% and LOB was calculated to be 2.3%.

12.9 Stability- Real-Time

A real time shelf life stability study was performed for MEDIDAS HbA1c using the A1c GEAR analyzer. From these results, it was concluded that the reagent cartridge can be stored for up to one year at 2-8 °C (36-46 °F).

13 Conclusions

Performance studies were conducted and the data obtained indicate the A1c GEAR System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 4, 2014

SAKAE CORPORATION
C/O ERICA AMMIRATI
575 SHIRLYNN COURT
LOS ALTOS CA 94022

Re: K130014
Trade/Device Name: A1c Gear System
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: II
Product Code: LCP, JJE
Dated: March 28, 2014
Received: March 31, 2014

Dear Ms. Ammirati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K130014

Device Name
A1c GEAR System

Indications for Use *(Describe)*
The A1c GEAR System is intended for in vitro diagnostic use only for the quantitative measurement of the percent hemoglobin A1c (%HbA1c) from finger-stick blood or venous whole blood collected in either EDTA or sodium fluoride (NaF) for clinical laboratory and point of care use. The measurement of HbA1c is recommended to monitor long-term glycemic control of persons previously diagnosed with diabetes mellitus. This test is not for screening or diagnosis of diabetes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Katherine Serrano -S

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